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REMARKS

Claims 1 through 11 and new Claims 12 through 15 are pending in the application.

Claim 1 has been amended to emphasize that the inventive agents advantageously provide a greater reduction in the cholesterol level than the sum of the effects when the carob fiber or n-3 fatty acid are administered alone. Support for this amendment can be found in the Application-as-filed, for example on Page 6, lines 13 through 15; Page 12, line 12; Page 13, lines 18 through 28.

Claim 2 has been amended to reflect advantageous embodiments in which the n-3 fatty acid is a single polyunsaturated fatty acid having a chain length $> C_{12}$. Support for this amendment can be found in the Application-as-filed.

Claim 4, reflecting beneficial embodiments in which the n-3 fatty acid is all-cis-4,7,10,13,16,19-docosahexaenoic acid (DHA), has been amended to depend from Claim 2. Support for this amendment can be found in the Application-as-filed.

Claims 10 and 11 have been amended to correct a typographical error. Support for this amendment can be found in the Application-as-filed.

Claims 12 through 15 have been added to complete the record for examination and highlight particularly advantageous embodiments of the invention.

Claim 12 reflects advantageous embodiments in which the water-insoluble carob fiber is administered in a daily dose ranging from 1 to 15 g. Support for Claim 12 can be found in the Application-as-filed, for example on Page 12, lines 5 through 10.

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Claim 13 reflects advantageous embodiments in which the n-3 fatty acid is derived from vegetable oil or oils from microorganisms. Support for Claim 13 can be found in the Application-as-filed, for example on Page 11, lines 12 through 14.

Claim 14 reflects advantageous products of the invention in which the n-3 fatty acid consists of one or more of: all-cis-9,12,15-octadecatrienoic acid (ALA), all-cis-6,9,12,15-octadecatetraenoic acid, all-cis-11,14,17-eicosatrienoic acid, all-cis-13,16,19-docosatrienoic acid, all-cis-7,10,13,16,19-docosapentaenoic acid (DPA) and all-cis-4,7,10,13,16, 19-docosahexaenoic acid (DHA). Support for Claim 14 can be found in the Application-as-filed, for example in Claim 3 as-filed.

Claim 15 reflects advantageous embodiments in which synergy is provided by n-3 fatty acid administered in a daily dose ranging from 50 mg to 600 mg. Support for Claim 15 can be found in the Application-as-filed, for example on Page 12, lines 1 through 3 and lines 11 through 19 and Page 15, line 9.

Reexamination and reconsideration of this application, withdrawal of all rejections, and formal notification of the allowability of the pending claims are earnestly solicited in light of the remarks which follow.

Submission of Terminal Disclaimer

Claims 1 through 11 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting in light of co-pending Application No. 10/539,174. Solely to advance prosecution of the case and without addressing the merits of the rejection, Applicants respectfully submit herewith a terminal disclaimer, as suggested by the Examiner. More particularly, Applicants submit herewith a terminal disclaimer that disclaims the terminal part of any patent granted on the above-identified application extending beyond the expiration date of

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the full statutory term which may ultimately result from any patent granted from the cited co-pending application, i.e. Application No. 10/539,174.

Applicants thus respectfully request withdrawal of the foregoing double patenting rejection upon entry of the enclosed terminal disclaimer.

*The Claimed Invention is Patentable
in Light of the Art of Record*

Claims 1 through 11 stand rejected over United States Patent No. 5,856,313 ("US 313") to Marco et al. in combination with United States Patent No. 5,502,077 ("US 077") to Breivik et al.

It may be useful to briefly consider the invention before addressing the merits of the rejection.

Broad sections of the population currently suffer from elevated blood cholesterol values. A number of therapeutic active compounds are prescribed for treating high cholesterol, including statins and the like. All of such therapeutic active compounds must be taken under medical supervision and monitoring.

A number of food components are known to positively effect cholesterol, as well. Unfortunately, the effects which can be achieved with such food components are significantly below those which are achieved using therapeutic active compounds, and are thus far lower than desirable. Furthermore, antagonistic actions have been found between combined food components. The combination of water insoluble carob fiber and viscous dietary fiber derived from carob seed meal has been shown to be detrimental to blood cholesterol levels, for example. (The Examiner's attention is kindly directed to the Application-as-filed at Page 5, lines 4 through 16).

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Altogether unexpectedly, Applicants have found that a combination of carob fiber and n-3 fatty acid provides a synergistic reduction in cholesterol levels and blood fat values.

Accordingly, the claims are directed to cholesterol-reducing agents that include water-insoluble carob fiber and at least one n-3 fatty acid, the n-3 fatty acid or the n-3 fatty acids being present at a concentration of at least 15 area % of TFA (area % based on the AOCS Official Method Ce 1b-69; TFA = total fatty acid). Surprisingly, the inventive agent provides a greater reduction in cholesterol level than the sum of the effects when the carob fiber and n-3 fatty acid are administered alone, as recited in the amended claims.

In advantageous embodiments, the synergy is imparted through use of single n-3 fatty acid having a chain length > C12, as recited in Claim 2 as-amended.

In beneficial aspects of such advantageous embodiments, the single n-3 fatty acid is all-cis-4,7,10,13,16,19-docosahexaenoic acid (DHA), as recited in Claim 4 as-amended.

The cited references do not teach or suggest the claimed invention.

US 313 is generally directed to methods of making carob fiber. US 313 discloses a nine step method of extracting water insoluble carob fiber from carob pods. (Col. 1, line 53 – Col. 3, line 44). US 313 expressly notes the particle size of flour made from its fiber. (Col. 4, lines 5 – 10). US 313 is curiously silent as to the length of the fibers it produces, however, other than a reference in its figure to “fine,” “medium” and “coarse” fiber. (Figure). US 313 merely generally indicates that carob fiber of indeterminate length, ingested alone, has a hypocholesterolaemic effect when provided as 5% of an animal's diet. (Col. 5, lines 1 - 28).

US 313 thus does not teach or suggest the claimed invention.

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US 313 specifically does not teach or suggest the recited synergistic cholesterol-reducing agent that includes a combination of a water-insoluble carob fiber and at least one n-3 fatty acid which provides a greater reduction in cholesterol level than the sum of the effects when the carob fiber or n-3 fatty acid are administered alone. Applicants respectfully make of record that, in contrast to the urgings of the Office Action, the recited components provide more than an "additive effect," as indicated numerous times in the Application-as-filed. MPEP 2144.09 (presence of synergy rebutting *prima facie* obviousness rejection).

Nor does US 313 teach or suggest the advantageous inventive agents in which synergy is imparted by a single n-3 fatty acid having a chain length > C12, as recited in Claim 2.

Thus US 313 most certainly does not teach or suggest such agents in which the n-3 fatty acid is all-cis-4,7,10,13,16,19-docosahexaenoic acid (DHA), as recited in Claim 4.

Nor does US 313 teach or suggest the administration of the advantageous inventive agent containing carob in a daily dose ranging from 1 to 15 g, as recited in Claim 12. US 313 instead discloses the administration of carob in significantly higher dosages, i.e. at 5% of an animal's daily diet. Applicants respectfully submit that the USDA's recommended 2000 calorie diet contains approximately 466 g of nutrients. Accordingly, US 313's percentage converts into a daily weight dosage of approximately 23 g of fiber per day, or 35% more fiber than recited within the advantageous embodiments of Claim 12.

US 313 likewise fails to teach or suggest the advantageous embodiments of Claims 13 through 15.

Accordingly, Applicants respectfully submit that US 313 does not teach or suggest the claimed invention, considered either alone or in combination with the remaining art of record.

US 077 does not cure the deficiencies in US 313.

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US 077 is directed to a particular mixture of DHA and EPA fatty acids which are said to have a positive effect on the risk factors for cardiovascular diseases. (Col. 2, lines 50 – 56 and lines 63 – 67). US 077 expressly indicates that “[t]o our knowledge there is nothing to suggest that DHA alone has any effect on the blood pressure.” (Col. 2, lines 26 – 27). US 077 similarly notes several earlier studies disclosing that EPA alone does not have a significant effect on hypertension. (Col. 2, lines 1 – 16). The DHA/EPA fatty acid blend is formed by subjecting marine oil to numerous processes, including esterification, urea fractionation and molecular distillation. (Col. 3, lines 24 – 29). US 077 indicates that the fractionation removes esters having a chain length below C20. (Col. 3, lines 30 – 32). Distillation is then used to “upgrade” either the DHA or EPA fraction (as appropriate) into the required 1:1 to 2:1 ratio. (Col. 3, lines 60 – 65). US 077’s working examples indicate that about 5 g of its fatty acid mixture is administered daily. (Col. 6, lines 49 – 58).

US 077 likewise fails to teach or suggest the recited synergistic cholesterol-reducing agents that include a combination of a water-insoluble carob fiber and at least one n-3 fatty acid which provide a greater reduction in cholesterol level than the sum of the effects when the carob fiber or n-3 fatty acid are administered alone. In fact, US 077 teaches away from the beneficial synergies between carob and fatty acid by instead touting a combination of fatty acids as providing advantageous results.

Nor does US 077 teach or suggest the advantageous agents of Claim 2, in which the synergistic effect is imparted by a single n-3 fatty acid having a chain length > C12, for numerous reasons. US 077 clearly indicates that all fatty acids having chain lengths of less than 20 are removed from its marine oil. Furthermore, to modify US 077 so as to avoid the required inclusion of two fatty acids would clearly render US 077 unfit for its intended purpose. MPEP 2143.01 (citing *In re Gordon*, 221 USPQ 1125 (Fed. Cir. 1984)).

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Thus US 077 most certainly does not teach or suggest such agents in which the single n-3 fatty acid is all-cis-4,7,10,13,16,19-docosahexaenoic acid (DHA), as recited in Claim 4.

US 077 likewise can not teach or suggest the advantageous inventive agents in which the n-3 fatty acid consists of one or more of: all-cis-9,12,15-octadecatrienoic acid (ALA), all-cis-6,9,12,15-octadecatetraenoic acid, all-cis-11,14,17-eicosatrienoic acid, all-cis-13,16,19-docosatrienoic acid, all-cis-7,10,13,16,19-docosapentaenoic acid (DPA) and all-cis-4,7,10,13,16,19-docosahexaenoic acid (DHA), as recited in Claim 14.

Nor does US 077, directed to method of processing marine oil, teach or suggest the advantageous inventive agents in which the n-3 fatty acid is derived from vegetable oil or oils from microorganisms, as recited in Claim 13.

US 077 further does not teach or suggest the advantageous administration of an agent containing carob in a daily dose ranging from 1 to 15 g, as recited in Claim 12.

And US 077 most certainly does not teach or suggest the synergy provided by the advantageous administration of an agent containing n-3 fatty acid in a daily dose ranging from 50 mg to 600 mg, as recited in Claim 15. US 077 instead teaches away from such embodiments by disclosing the daily administration of approximately 5 g within its working examples.

Accordingly, Applicants respectfully submit that US 077 does not teach or suggest the claimed invention, considered either alone or in combination with US 313.

There would have been no motivation to have combined US 313 and US 077. Applicants respectfully submit that merely because the references can be combined is not enough, there must still be a suggestion. MPEP 2143.01 (section citing Mills). US 313 is directed to methods of making carob flour. US 077 is directed to methods by which to produce a particular fatty acid

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blend from marine oil. These are altogether different fields of endeavor and problems solved, to say the least.

Applicants respectfully submit that the Office Action is instead indulging in impermissible hindsight by merely picking and choosing elements from the prior art while using the instant specification as the guide for that selection process. In particular, an antagonistic action was found for food component mixtures including the recited water insoluble carob fiber, as noted above. Consequently, there would have been no motivation to have combined the insoluble carob fiber with another food component as there would have been no expectation of success.

However, even if combined (which Applicants submit should not be done), the claimed invention would not result.

The combination specifically fails to teach or suggest that the recited synergistic cholesterol-reducing agents including a combination of a water-insoluble carob fiber and at least one n-3 fatty acid would provide a greater reduction in cholesterol level than the sum of the effects when the carob fiber or n-3 fatty acid are administered alone. As noted above, water-insoluble carob fiber was known at the time of the invention to provide an antagonistic effect when combined with additional food components. Thus, in contrast to the urgings of the Office Action, there would have been no reasonable expectation of success upon the combination of water-insoluble carob fiber and an additional food component.

Furthermore, the secondary reference clearly teaches away from the unexpected synergy between carob and fatty acid by instead indicating that synergy is provided by its combination of particular fatty acids in specific ratios.

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Accordingly, the combination most certainly does not teach or suggest the advantageous agents of Claim 2, in which a synergistic effect is imparted by a single n-3 fatty acid having a chain length > C12. The secondary reference, cited by the Office Action for its use of fatty acids, clearly indicates that all fatty acids having chain lengths of less than 20 are removed from its marine oil. Furthermore, to modify the secondary reference so as to avoid the required inclusion of two fatty acids would clearly render it unfit for its intended purpose, as noted above.

Thus the combination most certainly does not teach or suggest such agents in which the single n-3 fatty acid is all-cis-4,7,10,13,16,19-docosahexaenoic acid (DHA), as recited in Claim 4.

The combination likewise can not teach or suggest the advantageous inventive agents in which the n-3 fatty acid consists of one or more of: all-cis-9,12,15-octadecatrienoic acid (ALA), all-cis-6,9,12,15-octadecatetraenoic acid, all-cis-11,14,17-eicosatrienoic acid, all-cis-13,16,19-docosatrienoic acid, all-cis-7,10,13,16,19-docosapentaenoic acid (DPA) and all-cis-4,7,10,13,16,19-docosahexaenoic acid (DHA), as recited in Claim 14.

Nor does the combination, whose secondary reference (US 077) is directed to methods of processing marine oil, teach or suggest the advantageous inventive agents in which the n-3 fatty acid is derived from vegetable oil or oils from microorganisms, as recited in Claim 13.

And the combination, disclosing a dosage of 5 % of daily diet for carob within US 313 and 5 g daily of a combination of particular acids in specific ratios in US 077, most certainly does not teach or suggest the beneficial synergistic amounts of the invention, such as the carob amounts of Claims 12 and n-3 fatty acid amounts of Claim 15.

Accordingly, Applicants respectfully submit that Claims 1 through 15 are patentable in light of US 313 and US 077, considered either alone or in combination.

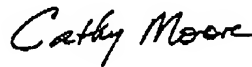
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CONCLUSION

It is respectfully submitted that Applicants have made a significant and important contribution to the art, which is neither disclosed nor suggested in the art. It is believed that all of pending Claims 1 through 15 are now in condition for immediate allowance. It is requested that the Examiner telephone the undersigned if any questions remain to expedite examination of this application.

It is not believed that extensions of time or fees are required, beyond those which may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time and/or fees are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required is hereby authorized to be charged to Deposit Account No. 50-2193.

Respectfully submitted,




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